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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/810,660 03/19/01 VASQUEZ LIPI

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EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/810,660

Applicant(s)

VASQUEZ LIPI, ROMAN EFRAIN

Examiner

Alysia Berman

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 09/231,837, and filed January 15, 1999. A reference to the prior application must be inserted as the first sentence of the specification of this application if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A topical product is not considered statutory subject matter. Amendment of the claim to read "A topical composition" would overcome this rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition, cream or ointment, does not reasonably provide enablement for a topical product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as written encompass products such as transdermal patches. There is no disclosure in the instant specification of transdermal patches. The specification is only enabling for a composition or more specifically a cream or ointment as disclosed at page 9, lines 28-32.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1-23 are indefinite because it is unclear what Applicant intends to encompass by a "topical product". What type of topical product does Applicant intend to claim? The metes and bounds of the claims cannot be determined.

9. Claim 1 is vague and indefinite because it is unclear if the topical product can contain only those components recited in the claim. The accepted language to denote open or closed claims is "comprising" and "consisting of", respectively. Amendment of the claim to recite "an oleaginous base comprising" if the product may contain other

components or "an oleaginous base consisting of" if the product must contain only those components recited is suggested to overcome this rejection.

10. Claim 2 is indefinite because it recites percents without units. Are the percents of components based on weight, volume or another type of measurement?

11. Claims 10, 12 and 14 are indefinite because they do not have units of measurement after "1275", "10.625" and "975", respectively. Is Applicant's intent to claim grams, milligrams, micrograms etc.?

12. Claim 13 is indefinite because it recites "between about 21.25 g Vitamin D."

13. Claim 13 is indefinite because it recites 21.25 g Vitamin D, but depends from claim 12, which recites micrograms of Vitamin D.

14. Claim 21 is indefinite because it is unclear how Applicant intends to further limit the claims. Claim 21 depends from claim 20 but recites the exact same limitation.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

16. Claims 1, 3, 6-9, 16, 17 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Guillon (US 4386067).

Guillon discloses a composition comprising commonly used oils such as sunflower, almond, olive, castor, and fish-liver oils (col. 2, lines 39-51 and claims). For beeswax, liquid petroleum jelly (mineral oil) and their amounts, see the examples. Applicant discloses at page 4, lines 23-25 that cod liver oil contains vitamins A and D and page 5, lines 4-7 of the specification that sunflower oil contains vitamin E. Applicant further discloses that it is preferable to employ the vitamins in the composition from natural sources. See page 5, lines 31-33 of the specification. Therefore, a composition that contains cod liver oil and sunflower oil would inherently contain vitamins A, D and E. The reference reads on the claims directed to the composition further comprising these vitamins.

17. Claims 3, 4, 6-9 and 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by McGinity et al. (US 5597849).

McGinity et al. disclose a composition comprising beeswax, mineral and castor oils, petrolatum and butylhydroxytoluene (BHT)(claims). Sunflower oil is disclosed at column 7, line 66. Stearic acid and cod liver oil are disclosed at column 9, lines 57-61. The beeswax is about 15-17% of the composition (examples). The composition contains from about 1-40% oils of any combination (col. 9, lines 58-62). Regarding the vitamins, see above.

18. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Lane (US 5503825).

Lane discloses a composition comprising petrolatum, castor, almond, olive, sunflower, and cod liver oils, and beeswax (col. 4, lines 21-40).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 1-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guillon.

Guillon discloses all of the limitations of the claims as stated above. Guillon does not disclose BHT or all of the percents of components as instantly claimed. Guillon does disclose preservatives in general. BHT is a commonly known and used preservative in the cosmetic and pharmaceutical art. Therefore, the use of BHT is not given patentable weight, absent evidence of unexpected results. It is considered within the skill in the art to select optimal parameters of a composition, such as percents of components, in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215, (CCPA 1980).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use BHT as the preservative and select optimal parameters in the composition of Guillon with the reasonable expectation of providing a preserved cosmetic composition with increased activity of the natural active principles contained in the various oils.

21. Claims 1-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane.

Lane discloses all of the limitations as stated above. Lane does not disclose BHT or the percents instantly claimed. Lane does teach preservatives in general. BHT is a commonly known and use preservative in the cosmetic and pharmaceutical art. Therefore, the use of BHT is not given patentable weight, absent evidence of unexpected results. It is considered within the skill in the art to select optimal parameters of a composition, such as percents of components, in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215, (CCPA 1980).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use BHT as the preservative and select optimal parameters in the composition of Lane with the reasonable expectation of providing a topical composition with improved healing properties.

22. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Guillon or Lane each in view of McGinity et al.

Guillon and Lane each disclose all of the limitations of the claims as stated above. Guillon and Lane each do not disclose stearic acid, butylhydroxytoluene (BHT), or all of the percents of components. Guillon teaches preservatives and other common additives in the examples. Lane teaches common additives such as preservatives at column 4, lines 54-67.

McGinity et al. teach stearic acid, BHT, and some of the amounts of the components as instantly claimed (see above). It is considered within the skill in the art to select optimal parameters of a composition, such as percents of components, in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215, (CCPA 1980).

It would have been obvious to one of ordinary skill in the art to use stearic acid and BHT as taught by McGinity et al. in the composition of either Guillon or Lane with the reasonable expectation of providing a topical composition that is convenient to use.

Claim Objections

23. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 depends from claim 20 but does not further limit claim 20 because both claims recite "further comprising sunflower oil".


Correspondence

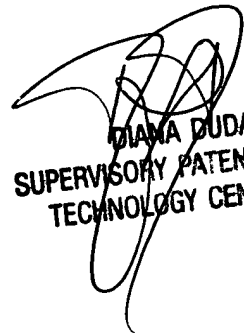
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4556 for regular communications and 703-308-7922 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysja Berman
Patent Examiner
June 4, 2001


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